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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/801,868

03/16/2004

Qun-Sheng Ji

OS-10002

8803

38724 7590 05/12/2009

OSI PHARMACEUTICALS, INC.
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EXAMINER

PAK, MICHAEL D

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

05/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/801,868	Applicant(s) JI, QUN-SHENG	
	Examiner Michael Pak	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,6,7,10-12,15-20,23 and 26-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,6,7,10-12,15-20,23 and 26-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Amendment filed February 20, 2009 has been entered.
2. Applicant's arguments filed February 20, 2009, have been fully considered but they are not found persuasive.
3. Claims 2, 4-5, 8-9, 13-14, 21-22, 24-25, and 36-37 are cancelled. Claims 1, 3, 6-7, 10-12, 15-20, 23 and 26-35 are examined below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3, 6-7, 10-12, 15-20, 23, and 26-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the

time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Newly amended claims encompass or recite the term “wherein human Ret receptor kinase has a protein sequence as published in the genetic sequence database GENBANK” which is new matter not disclosed in the specification. Applicants argue that paragraph 32 of the specification disclose the claim amendment. However, the paragraph 32 of the specification does not disclose the new claim amendment.

5. Claims 1, 3, 6-7, 10-12, 15-20, 23, and 26-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the claims are not clear because the amended claim limitations recite specific location of the substitution of amino acids but the specific structure of the sequence is not provided. Thus the term by name only encompass variants which will change the numerical location of the amino acids in the protein and thus renders the terms relative. Furthermore, claims recite receptors by name only which is ambiguous because no structure is provided and the metes and bounds of the term is not clear. Claimed term “Ret receptor kinase” by name only without structure is ambiguous because the metes and bounds of the term is not clear. The term is not defined and the boundary of the term is not clear. Other receptor domains are also recited by name only without structure and the metes and bounds are not clear. The recitation of the nomenclature of specific species does not render the name of Ret

receptor kinase clear because the metes and boundary of the term is not defined by the nomenclature. Many of the species not within the nomenclature have similar or same function or cross function, thus creating confusion around the term.

Applicants argue that there are only two human ret receptor kinase sequence in Genbank and thus is clear. However, report attached with the applicant's response names the sequence "ret proto-oncogen" which is not disclosed in the specification. Thus, the claims appear to encompass many different names which includes many other kinases since the name only discloses the function by name.

Applicants argue that numbering is identical to genbank sequence. However, the claimed term encompass variants as well as the genbank sequences and thus a mutation of deletion or addition of sequence will vary the numbering of the sequence which renders relative position ambiguous.

It should be noted that most scientific articles or nomenclature do not discuss the metes and bounds of the generic term but are discussing the specific species in a particular reference. Applicants arguments appear to agree that the term encompasses variation in structure even though no reference structure is provided in the claim to set the metes and boundary of the term. Furthermore, there are many different types of mutations of Ret kinase species in the literature. If the function is not provided with structure which is sufficient to narrow the claims then the metes and bounds are not clear. For example when is a Ret receptor kinase which can have unlimited substitution different from any other kinase receptor? For example the EGFR is a kinase receptor and appears to meet the limitations of the Ret receptor kinase as claimed without

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structural limitation. Thus, how is one skilled in the art to determine when Ret receptor kinase is different from other receptor kinases if it is not limited by structure.

Furthermore, the names of receptors change over time or are named differently by different inventors or scientists thus it becomes a relative term. Furthermore, if the Ret kinase receptor can have unlimited changes then how is one skilled in the art able to determine what is the specific amino acid sequence number that should be substituted. Furthermore, if the Ret receptor kinase can have unlimited mutations then when is Ret kinase receptor a rat receptor versus the human receptor or any other species.

6. No claim allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:00 - 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael Pak/
Primary Examiner, Art Unit 1646